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10/627,114

07/25/2003

Peter Paul Zilla

P-8794.05 Continuation 2

3869

7590

11/29/2006

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EXAMINER

WILLSE, DAVID H

ART UNIT

PAPER NUMBER

3738

DATE MAILED: 11/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/627,114

Applicant(s)

ZILLA ET AL.

Examiner

Dave Willse

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 71-87 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 71-87 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

The disclosure is objected to because of the following informalities: The prior application data at the beginning of the specification must be updated.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 71, 72, 74, 76, 78, 79, and 82-84 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Alt, US 2004/0039438 A1. The scaffold **32** includes interconnected pores bordered by microspheres bonded to one another; said pores are defined by surfaces that are spherically concave (Figure 2; paragraph **0033**; etc.) and thus uniformly shaped. The ingrowth matrix generally involves drugs incorporated in a biodegradable carrier (e.g., paragraph **0041**) and comprises a concentration gradient by virtue of the larger reservoir or repository toward the

base layer **30** (paragraphs **0011**, **0034**, and **0040**). Regarding claims 74, 76, 78, and 79, viruses and genes (abstract, last sentence; paragraphs **0042** and **0044**) inherently possess proteins and peptides. Regarding claim 82, the stent may take on a helical form (paragraphs **0021** and **0030**), wherein the interconnecting channels would collectively be helically oriented. Regarding claim 83: paragraph **0031**. Regarding claim 84, the term “spherical” means “[o]f or pertaining to a sphere” (*Webster’s II New Riverside University Dictionary*, 1984); the pore shapes pertain to a sphere in that they are defined by adjacent microspheres.

Claims 73, 75, 77, 80, 81, and 85-87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alt, US 2004/0039438 A1. Regarding claim 73, hydrogels were well known in the art at the time of the present invention and would have been obvious in order to contain medicaments in solution. Regarding claims 75, 77, and 80, materials such as collagen and growth factor would have been obvious in order to facilitate endothelial cell growth and/or gene transfer. Regarding claim 81, polyethylene glycol was well known as a base for pharmaceuticals and would thus have been obvious to the ordinary practitioner for carrying certain types of drugs. Regarding claims 85-87, stents are commonly used for affixing vascular grafts and heart valves (including sewing rings) within the circulatory system; to incorporate the Alt coating system into such stents would have been obvious in order to provide drug delivery when indicated.

The Applicant’s remarks have been considered but are deemed moot in view of the new grounds of rejection presented above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dave Willse whose telephone number is 571-272-4762 and who is generally available Monday through Thursday and often on Friday. If attempts to reach the

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examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



**Dave Willse**  
**Primary Examiner**  
**Art Unit 3738**